



Battelle

Pacific Northwest Laboratories

Project Number PNL-9181

Internal Distribution
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Date **September 24, 1973**

To **W. J. Bair**

From **K. L. Swinth**

Subject **Human Testing of Esophageal Probe**

REPOSITORY PNL
COLLECTION Intraesophageal
BOX No. 2947
FOLDER HSC 73-5

Dear Bill,

Below I have outlined the general scheme concerned with the measurements we intend to perform at Los Alamos in cooperation with their medical people. They have selected about 12 likely candidates and will narrow this to two or three as soon as the Battelle review is completed. The candidates have not been interviewed to avoid a growing impatience on their part. I would assume that they will be requested to finish the informal consent form at this time if they show a willingness to cooperate in the measurement. You should have copies of the consent form and IASL's review. I believe our interest is third party and would like to meet with the committee as soon as possible to expedite this matter.

Before I outline the tentative protocol I would like to point out that the medical people at IASL will assume medical management and must manage the procedure in a manner which, in their judgement, will minimize the discomfort and risk to the subject. For our efforts (BNW) we need an x ray to verify probe position and counts at the bifurcation and 4cm above and below this position to estimate the lymph node burden.

Protocol

Outlined below is the present experimental protocol. Medical aspects must be the decision of the attending physician; however, the expected procedure is outlined.

1) At least one hour prior to the measurement the probe and associated electronics will be turned on and tested to ascertain that the equipment is operating properly. This consists of checking electronic settings and counting a standard source in a fixed geometry. A series of room backgrounds will then be taken until the measurement begins.

2) During the equipment preparation the physician will interview the subject making sure he understands the procedure and to determine any possible contraindications. An acceptable informed consent form will be

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required before the experiment proceeds. (In all probability this portion of the procedure will have been completed in the past).

3) Next the subject will be administered a local anesthetic if deemed proper by the physician and requested by the subject. Either a flavored viscous jell containing xylocaine and made for this purpose or a topical anesthetic spray could be used.

4) After the anesthetic (if used) has taken effect the probe will be lightly lubricated with a hospital lubricant and inserted down the esophagus 27cm as referenced to the incisors.

5) In order to verify position of the probe an x ray will be taken of the area of interest. If not in correct position adequate corrections will be possible without a second x ray. The detector will be in correct position when its distal end is about 1cm below the common segment of the major bronchi.

6) Next the subject will be placed in a comfortable position and two 10 minute recordings of the count rate will be made. (At IASL the initial positioning and x ray will be done in the hospital after which the subject will be moved to the adjacent building where the whole body counter is located. As I understand it the subject would be transported between locations in a wheel chair. Whether or not the probe is in location during transport will depend on his tolerance of the insertion procedure. Reinsertion to the proper depth will not be difficult.) The probe will then be inserted an additional 4cm for a 10 minute count and then withdrawn 8cm for a final 10 minute count.

7) Following completion of the counts the probe will be withdrawn and the subject will be examined by the physician. The physician will also communicate any preliminary findings to the subject if available.

8) Additional room backgrounds and a count of the calibration source will be made following the measurement.

As pointed out in previous communications, the risk from esophagoscopy is small and the probe does not present any hazards that I can foresee. It is passive in nature, the materials are non toxic, and the inserted portion is one integral unit which could not come apart in any foreseeable event.

I would be glad to discuss these aspects in more detail.

Sincerely yours,

Ken p.s.

Ken Swinth